Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

A comparison of efficacy of oral prednisolone plus tacrolimus and azathioprine in the treatment of pemphigus vulgaris patients

Protocol summary

Summary

Pemphigus vulgaris is a chronic autoimmune mucocutaneous bullous disease that can cause death if left untreated. Systemic corticosteroid in combination with imunosuppressive are the mainstay of therapy, however it is unclear which adjuvant drugs is superior overall. Azathioprine is the most used drug in Shiraz dermatology center; unfortunately it has bone marrow suppression and carcinogenic properties. Tacrolimus has been used for pemphigus, successively, in one case reports and a study on mice. It has favorable side effects compared to azathioprine. 46 pemphigus patients will be divided into 2 groups. The control group will receive prednisolone and azathioprine, and the other 23 patients will receive prednisolone and tacrolimus for a minimum of 6 months. Pemphigus activity scores, the time that new bulla formation stopped, and the time corticosteroid is tapered, will be documented and analyzed in 2 groups. The side effects of medications will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012073010450N1**
Registration date: **2013-02-23, 1391/12/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-02-23, 1391/12/05

Registrant information

Name

Maryam Sadat Sadati

Name of organization / entity

Shiraz University of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1627 8419

Email address

sadatim@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz university of medical sciences

Expected recruitment start date

2010-04-01, 1389/01/12

Expected recruitment end date

2012-03-31, 1391/01/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of efficacy of oral prednisolone plus tacrolimus and azathioprine in the treatment of pemphigus vulgaris patients

Public title

A comparison of efficacy of oral prednisolone plus tacrolimus and azathioprine in the treatment of pemphigus vulgaris

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 46 patients from 20 to 80 years old; new pemphigus vulgaris or new disease activity; the clinical diagnosis of pemphigus vulgaris will be based on clinical presentation and histological analysis (+/- immunofluorescences study) of at least 1 biopsy specimen from the skin or the mucosa. Exclusion criteria: Having contraindications for the use of azathioprine,

tacrolimus or prednisolone; any history of hypersensitivity to these drugs; active infection; pregnancy; lactation or no ability to attend follow-up; severe side effect during the study period.

Age
From **20 years** old to **80 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences

Street address
Zand street

City
Shiraz

Postal code

Approval date
2012-04-05, 1391/01/17

Ethics committee reference number
cc-91-2849

Health conditions studied

1

Description of health condition studied
pemphigus vulgaris

ICD-10 code
L10.0

ICD-10 code description
Pemphigus vulgaris

Primary outcomes

1

Description
arrest of disease progression

Timepoint
2 months

Method of measurement
arrest of new bulla fromation, 70% re-epithelization

Secondary outcomes

1

Description
remission of the disease

Timepoint
6-8 months

Method of measurement
no new bulla and no disease activity

Intervention groups

1

Description
Control group will receive azathioprine 2.5 mg/kg and prednisolone 1 mg/kg every day with gradual tapering of steroid during the follow up period.

Category
Treatment - Drugs

2

Description
Intervention group will receive tacrolimus 0.03 mg/ kg and prednisolone 1 mg/kg with gradual tapering of steroid during the follow up.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dermatology ward and cutaneous leishmaniasis research center, Shiraz University of Medical Sciences

Full name of responsible person

Street address

City
Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Mr. Eskandari

Street address
Zand street
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Maryam Sadati
Position
MD, dermatology resident
Other areas of specialty/work
Street address
Shiraz University of Medical Sciences, Dermatology department, Zand street
City
Shiraz
Postal code
Phone
+98 71 1231 9049
Fax
Email
msadati63@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences, Dermatology ward
Full name of responsible person
Dr. Ladan Dastgheib
Position
MD
Other areas of specialty/work
Street address
Shiraz University of Medical Sciences, Zand street
City
Shiraz
Postal code
Phone
+98 71 1231 9049
Fax
Email
dastghl@sums.ac.ir
Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty